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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,510	03/30/2004	Stephen J. Petti	2098.003	3250

23405 7590 09/11/2007

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EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
09/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,510	PETTI ET AL.	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4 and 6-11 are presented for examination on the merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 13, 2007, has been entered. The amendment filed June 13, 2007, has been received and entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernd Elger et al, cited on enclosed PTO-1449 Form, in view of Schwartz et al (US 5523292), cited on enclosed PTO-892 Form.

Claims are drawn to a method for treating stroke in a patient by administering ancrod intravenously at varied time intervals and in effective amounts, therefore.

Elger et al (Elger) teach a method for treating stroke in a patient by administering ancrod intravenously at varied time intervals and in effective amounts, therefore. Note page 895, summary section.

Schwartz et al (Schwartz) teach a method for preventing restenosis by administering ancrod intravenously at varied time intervals and in effective amounts, therefore. Note col. 2, lines 54-67 and col. 3-4, lines 1-20. Also note col. 6, line 60.

The claims differ from Elger in that the specific time intervals and effective amounts are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat stroke with ancrod as disclosed by Elger by selecting for the time intervals and effective amounts which have proven efficient in preventing restenosis which is also related to the onset of stroke in a patient. Clearly with successful dosages and time intervals taught by Schawrtz one of skill would have expected successful results for treating stroke as ancrod is known to be effective but the

amounts disclosed by Schwartz would have motivated one of skill to select and administer these amounts to a stroke patient as well for treatment therefore.

The identical effective range amounts are disclosed by Schwartz and for one of skill to glean what has already been performed in the art for one disease is clearly an obvious moficiation of the cited prior art. Each of the claim features are disclosed by Schwartz but he is not treating stroke per se. One of skill would have expected that the amounts would work because the same identical compound is useful to treat stroke patients. Further, the amounts administered by Applicants' claimed methods are disclosed by Schawartz to be generally known in the art, note col. 2, lines 65-67. In the absence of persuasive evidence to the contrary the claims are prima facie obvious.

Response to Arguments

Applicant's arguments filed June 13, 2007, have been fully considered but are not deemed persuasive. The argument that Elger does not teach the claimed range is noted, however, at page 897, column 1, lines 1-10, the reference does clearly suggest that positive results have been obtained for decreasing fibrinogen levels within the range from above 1 IU kg/hour to about 10 IU kg/hour. Thus, while reduction in lesions is not discussed a reduction of fibrinogen levels is clearly described with the claimed range. Therefore, one of skill would have expected to be able to achieve initial defibrinogenation as claimed. Ancrod is well known to cleave fibrinogen leading to rapid defibrinogenation, as disclosed by Elger. Further, the instants claims do not require a reduction in lesion volume on the brain but a reduction in fibrinogen levels via administering a defibrinogenating agent.

Elger combined with Schwartz clearly does disclose capability at lower dosage concentration rates. The second argument that animal studies do not translate well to human studies of ischemic stroke is noted, however, the disclosed treatment schedule followed by Elger included administering ancrod 30 minutes after middle cerebral artery occlusion. Thus, there is at least a suggestion, if not a teaching, Elger does not require a 24 hour obversation period before beginning treatment via administration of ancrod to a potential patient. Animal models are often used to determine treatment regimens for humans.

Regarding the arguments directed at the teachings of Schwartz it should be noted that the ranges are within the range as claimed because 1 to 3 Units kg includes 1.25 Units per kg as claimed herein. Also as noted above ancrod is known to rapidly lower fibrinogen levels and hence this effect is intrinsic. Furthermore, there is overlap between the range disclosed by Elger and that disclosed by Schawartz. Each of the claimed process steps are either disclosed or are intrinsic to the processes of the cited prior art, as for example a ceasing of administration of the agent will intrinsically allow for normalization of fibrinogen levels to occur due to a leveling off effect after initial defribinogenation. The claims are prima facie obvious over the cited prior art for these reasons.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the previously enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

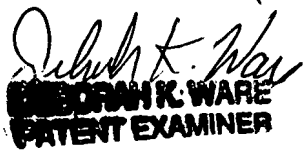
The remaining references listed on the previously enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah K. Ware
September 1, 2007